

REMARKS

Applicant respectfully requests reconsideration of the rejection of this application as examined pursuant to the office action of January 12, 2006. In the office action, Claims 1-4, 6-13, 17, 20, 24, 27-28, 45-49, 51-53, 55-57 and 63 were examined. Confirmation was provided that Claims 5, 14-16, 18-19, 21-23, 25-26, 29-44, 50, 54 and 58-62 were withdrawn from consideration. No new claims have been added by this amendment. Therefore, Claims 1-4, 6-13, 17, 20, 24, 27-28, 45-49, 51-53, 55-57 and 63 are pending.

Claims 1-2, 27-28, 45 and 63 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-2 and 16-17 of co-pending US Application Serial No. 10/884,015 including a common inventor. Claims 1-4, 6-13, 17, 20, 24, 27-28, 45-49, 51-53, 55-56 and 63 were rejected under 35 USC § 112, second paragraph, as being indefinite. Claims 1-3, 6-12, 27, 45-49, 53 and 63 were rejected under 35 USC § 102(b) as being anticipated by PCT application WO 01/89418 to Gabbay (“Gabbay”). Claims 1-4, 9-13, 17, 20, 24, 27-28, 45-46, 51-52, 57 and 63 were rejected under 35 USC § 102(b) as being anticipated by PCT application WO 01/47438 to Bessler (“Bessler”). Claims 55 and 56 were rejected under 35 USC § 103(a) as being unpatentable over Bessler or Gabbay in view of US Patent No. 6,210,432 to Solem et al. (“Solem”).

Claim Amendments

Applicant has taken this opportunity to amend elected independent Claims 1, 45, 57 and 63 of the application pending for consideration. Each of these claims was amended to make clear that the restraining component of the implantable device extends inwardly from the ring within the plane of the ring. These claims were further amended to describe the restraining component as being arranged to restrain prolapse movement of any one or more of the valve leaflets while minimizing leaflet contact, blood flow turbulence and blood flow obstruction. This arrangement of the restraining component distinguishes the present invention from the devices described in the references cited in the office action. The combination of the ring and the restraining member arranged in the manner indicated in the amended independent claims corrects valve annulus irregularities and further reduces the number and complexity of adjunctive procedures that may otherwise be required during cardiac valve repair. Specifically, the

restraining component restrains prolapse movement of any one or more of the valve leaflets (not just one of them), thereby minimizing separate or additional procedures to correct prolapse problems. Further, the restraining component is arranged to restrain prolapse movement while also minimizing leaflet contact, turbulence and flow obstruction within the heart. These modifications are fully supported in the original specification at page 16, paragraph [0052]. Applicant respectfully suggests that the devices of the cited references fail to resolve all of these concerns in a single implantable device.

The Provisional Double Patenting Rejections

In response to the provisional rejection of Claims 1-2, 27-28, 45 and 63 as being unpatentable over Claims 1-2 and 16-17 of co-pending Application No. 10/884,015, Applicant submits herewith a Terminal Disclaimer. Under the Terminal Disclaimer, Applicant requests that any patent issuing on the subject application will have a termination date corresponding to that of any patent issuing on the identified pending application.

In view of the filing of the Terminal Disclaimer, Applicant respectfully suggests that the provisional rejection of pending Claims 1-2, 27-28, 45 and 63 for double patenting has been successfully traversed. Withdrawal of that rejection is therefore requested.

The 35 USC § 112, Second Paragraph, Rejections

Pursuant to the recommendation made on page 3 of the January 12, 2006, office action, independent Claims 1, 45, and 63 have been amended to describe the restraining component as “extending inwardly from the ring.” In addition, Claim 1 has been amended to remove the description of the restraining structure as having an “inflow” restraining characteristic on the valve leaflet. Instead, the independent claims including Claim 1 are now directed to describing the restraining component as restraining prolapse movement of any one or more of the valve leaflets. Applicant notes, however, that use of the word “inflow” in the context of the orientation of the implantable device within the heart appears to have been correct in view of the direction of blood flow and the desire to restrain prolapse movement. In view of the amendments made to the noted claims, it is respectfully suggested that the rejection of Claims 1-4, 6-13, 17, 20, 24, 27-28, 45-49, 51-53, 55-56 and 63 under 35 USC § 112, second paragraph, has been addressed. Withdrawal of that rejection is therefore requested.

The 35 USC § 102(b) Rejections

Claims 1-3, 6-12, 27, 45-49, 53 and 63 of the application as previously amended were rejected as being anticipated by Gabbay. It is stated in the office action that the buttress (20) of Gabbay extends over a portion of the interior of a ring and that at least part of it is within the [plane] defined by the ring. Applicant respectfully disagrees with the general characterization that the present invention as claimed is anticipated by Gabbay and, more specifically, the characterization of the orientation of the Gabbay buttress with respect to the ring and the ring plane. The Gabbay ring is identified in the reference as the annular base portion 12. See line 16 of page 4 of the Gabbay reference. The Gabbay buttress “extends generally axially from and radially outwardly relative to the outflow side 18 of the base portion 12. An axial length of a portion 22 of the buttress 20 proximal the base portion 12 extends radially inwardly toward the axis 14 and generally axially away from the base portion. A distally extending portion 24 of the buttress 20 extends from the proximal portion 22 and curves radially outwardly therefrom for the remaining length of the buttress to terminate in a distal end 25.” See lines 8-14 of page 5 and figures 1, 3-5, 6-8, and 9-10 of the Gabbay reference, all of which clearly indicate that the buttress 20 is not within the plane of the ring. On the other hand, the implantable device of the present invention includes a restraining component that does extend inwardly within the plane of the ring.

For the reason indicated above, the present invention as described in the amended claims is clearly distinct from the Gabbay device. Further, the present invention as described in the amended claims also includes arrangement of the restraining component to restrain prolapse movement of any one or more of the two or more valve leaflets, but essentially enables the valve leaflets to coapt. The Gabbay device is limited, on the other hand, to establishing coaptation between a leaflet and the man-made buttress. While the buttress may be fabricated of a compatible material, its structure is not optimally suited for the intended purpose as it is likely to degrade over time, it is likely to cause irritation of the leaflet it is in contact with over a substantial area, or both.

Still further, the present invention as claimed in the amended independent claims includes the restraining structure configured to minimize leaflet contact, blood flow turbulence and blood flow obstruction. The design of the Gabbay repair apparatus clearly fails to incorporate such

characteristics. The Gabbay apparatus includes a substantial element, the buttress 20, which extends directly into the blood flow path transverse to the orientation of its connected ring. This positioning is likely to cause flow turbulence. The Gabbay apparatus also includes an element, the outer sheath, which is nonporous, extends into the blood flow path, and which establishes a substantial surface of man-made material in regular contact with the leaflet. The sheath can cause turbulence of blood flow and can constrict the flow of blood by blocking blood located behind it. The implantable device of the present invention does not extend into the blood flow pathway and is arranged to minimize leaflet contact as well as being a minimal disruption to blood flow volume and pattern.

Applicant respectfully notes that the amendments made to independent Claims 1, 45 and 63 and the arguments presented herein successfully traverse the rejection of currently pending Claims 1-3, 6-12, 27, 45-49, 53 and 63 under 35 USC § 102(b) based on the Gabbay reference. Withdrawal of that rejection is therefore requested.

Claims 1-4, 9-13, 17, 20, 24, 27-28, 45-46, 51-52, 57 and 63 of the application as previously amended were rejected as being anticipated by Bessler. It is stated in the office action that the restraining member of the present invention is met by the template 206 of Bessler. Applicant respectfully disagrees with the assertion that the present invention as described by the amended claims is anticipated by Bessler. The Bessler device illustrated in figures 9A and 9B of that reference (the only aspect of Bessler asserted in the January 12, 2006, office action) is a ring only, and therefore is not a ring having a restraining component. The Bessler template is used only when an annuloplasty ring is implanted. As indicated at page 14, lines 19-29, of the reference, the template is removed during the ring placement procedure. On the other hand, the restraining component of the device of the present invention is permanently affixed to the ring.

As described in the amended independent claims of the present application, the restraining component of the present invention “is arranged to restrain prolapse movement of any one or more of the valve leaflets while minimizing leaflet contact, blood flow turbulence and blood flow obstruction.” The template of the Bessler apparatus is not designed to restrain prolapse movement of any one or more of the valve leaflets while minimizing leaflet contact, blood flow turbulence and blood flow obstruction. Instead, the template serves only to help move the ring into place, and to help the surgeon while forming suture knots to secure the ring in

place. Bessler does not teach or suggest the template or an equivalent thereof to restrain prolapse movement of a valve leaflet and, instead, teaches away from it by stating that the template is to be removed during the ring implant procedure.

Applicant respectfully notes that the amendments made to independent Claims 1, 45, 57 and 63 and the arguments presented herein successfully traverse the rejection of currently pending Claims 1-4, 9-13, 17, 20, 24, 27-28, 45-46, 51-52, 57 and 63 under 35 USC § 102(b) based on the Bessler references. Withdrawal of that rejection is therefore requested.

The 35 USC § 103(a) Rejection

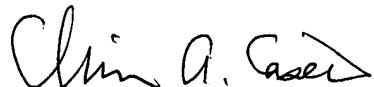
Dependent Claims 55 and 56 were rejected as being unpatentable over Bessler or Gabbay in view of Solem. Applicants note and repeat herein the arguments presented above regarding the Bessler and Gabbay references. In accordance with the examiner's remarks, the Solem reference is cited in the January 12, 2006, office action for the limited purpose of noting that annuloplasty rings may be made of a nickel-titanium alloy referred to by the name Nitinol. The Solem reference fails to teach or suggest an implantable device including a ring with a restraining component affixed to the ring and extending inwardly from the ring within the ring plane, and wherein the restraining component is arranged to restrain prolapse movement of any one or more of the valve leaflets while minimizing leaflet contact, blood flow turbulence and blood flow obstruction. The present invention as described by the amended claims, teaches such an implantable device. Applicant respectfully note that the amendment made to independent Claim 45, upon which Claims 55 and 56 dependent and the arguments presented herein regarding the Bessler, Gabbay and Solem references successfully traverse the rejection of currently pending dependent Claims 55 and 56 under 35 USC § 103(a). Withdrawal of that rejection is therefore requested.

CONCLUSION

In view of the foregoing amendments made to the independent claims, the remarks made herein and the filing of a provisional terminal disclaimer, Applicant respectfully suggests that the provisional double patenting rejection, and the rejections under 35 §§ 112, second paragraph, 102(b) and 103(a) have been successfully traversed. Allowance of pending Claims 1-4, 6-13, 17, 20, 24, 27-28, 45-49, 51-53, 55-57 and 63 is therefore requested.

By this amendment, no new claims have been added; therefore, no additional filing fee is required.

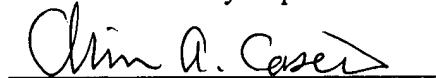
Respectfully submitted,



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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Fee Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on July 11, 2006. It is hereby requested that this filing be granted a filing date of July 11, 2006.



Chris A. Caseiro